|  | **Surgisis Anal Fistula Plug**(N=152) | **Surgeon’s Preference**(N=152) | **All** **Participants**(N=304) |
| --- | --- | --- | --- |
| **Minimisation Variables** |
| ASA grade P1 normal healthy patient  | 118 (78%) | 117 (77%) | 235 (77%) |
| P2 mild systemic disease | 31 (20%) | 30 (20%) | 61 (20%) |
| P3 severe systemic disease | 3 (2%) | 5 (3%) | 8 (3%) |
|  |
| Age at randomisation (years) <30 | 23 (15%) | 22 (15%) | 45 (15%) |
| 30-39 | 39 (26%) | 36 (24%) | 75 (25%) |
| 40-49 | 35 (23%) | 45 (30%) | 80 (26%) |
| 50-59 | 33 (22%) | 29 (19%) | 62 (21%) |
| 60-69 | 12 (8%) | 10 (6%) | 22 (7%) |
| ≥70 | 10 (6%) | 10 (6%) | 20 (6%) |
|  |
| Type of surgery Advancement Flap | 32 (21%) | 34 (22%) | 66 (22%) |
| Fistulotomy | 6 (3%) | 2 (1%) | 8 (2%) |
| Cutting Seton | 57 (38%) | 57 (38%) | 114 (38%) |
| LIFT Procedure | 57 (38%) | 59 (39%) | 116 (38%) |
|  |  |  |  |
| Secondary extensions at baseline EUA¹ | 19/107 (18%) | 17/105 (16%) | 36/212 (17%) |
| **Patient Characteristics** |
| Age at randomisation (years) Mean (SD, N) | 45.2 (14.1, 152) | 44.9 (13.7, 152) | 45.1 (13.9, 304) |
| Range | 20-83 | 18-80 | 18-83 |
|  |
| Sex Male | 86 (57%) | 81 (53%) | 167 (55%) |
| Female | 66 (43%) | 71 (47%) | 137 (45%) |
| Missing | 1 | 2 | 3 |
|  |  |  |  |
| Smoker | 35 (23%) | 38 (25%) | 73 (24%) |
| Missing | 1 | 2 | 3 |
| **St Mark’s Incontinence Score** |
| St Mark’s Incontinence Score² Median [IQR, N] | 4 [1-6, 151] | 4 [2-8, 152] | 4 [2-7, 303] |
| Range | 0-21 | 0-18 | 0-21 |
| **Fistula History** |
| First/Recurrent fistula First | 101 (70%) | 98 (70%) | 199 (70%) |
| Recurrent | 44 (30%) | 42 (30%) | 86 (30%) |
| Missing/Unknown³ | 7 | 12 | 19 |
|  |  |  |  |
| Previous fistula surgery | 64 (42%) | 73 (48%) | 137 (45%) |
|  |
| Number of previous fistula surgeries Median [IQR, N] | 2 [1-2, 63] | 1 [1-3, 73] | 2 [1-2, 136] |
| Range | 1-13 | 1-12 | 1-13 |
|  |
| Type of previous fistula surgery Fistulotomy | 10/63 (16%) | 13/73 (18%) | 23/136 (17%) |
| Seton | 57/63 (90%) | 64/73 (88%) | 121/136 (89%) |
| Advancement Flap | 2/63 (3%) | 2/73 (3%) | 4/136 (3%) |
| Fistula Plug | 0/63 (-) | 0/73 (-) | 0/136 (-) |
| Other | 11/63 (17%) | 23/73 (32%) | 34/136 (25%) |
| Missing | 1 | 0 | 1 |
| **EUA** |
| Length of primary tract (cm) Median [IQR, N] | 3.5 [3.0-4.0, 148] | 3.0 [2.5-4.0, 145] | 3.0 [3.0-4.0, 293] |
| Range | 1.5-12.0 | 1.5-8.0 | 1.5-12.0 |
|  |  |  |  |
|  |  |  |  |
| Level of internal opening in relation to dentate line |  |  |  |
| Below | 12 (8%) | 21 (14%) | 33 (11%) |
| At | 96 (64%) | 99 (66%) | 195 (65%) |
| Above | 43 (28%) | 30 (20%) | 73 (24%) |
| Missing | 1 | 2 | 3 |
|  |
| Extent of external sphincter involvement <1/3 | 18 (12%) | 20 (13%) | 38 (12%) |
| 1/3 | 5 (3%) | 3 (2%) | 8 (3%) |
| >1/3 | 127 (85%) | 127 (85%) | 254 (85%) |
| Missing | 2 | 2 | 4 |
|  |  |  |  |
| Secondary tracts | 17 (11%) | 19 (13%) | 36 (12%) |
| Missing | 1 | 2 | 3 |
|  |
| Number of secondary tracts Median [IQR, N] | 1.0 [1.0-1.0, 17] | 1.0 [1.0-1.0, 19] | 1.0 [1.0-1.0, 36] |
| Range | 1.0-1.0 | 1.0-1.0 | 1.0-1.0 |
|  |  |  |  |
| Supralevator extension | 4 (3%) | 4 (3%) | 8 (3%) |
| Missing | 1 | 2 | 3 |
|  |  |  |  |
| Horse-shoe extensions | 10 (7%) | 6 (4%) | 16 (5%) |
| Missing | 4 | 3 | 7 |
|  |  |  |  |
| Active infection/abscess | 27 (18%) | 26 (17%) | 53 (18%) |
| Missing | 1 | 2 | 3 |
|  |  |  |  |
| Seton inserted | 149 (99%) | 149 (99%) | 298 (99%) |
| Missing | 1 | 2 | 3 |
| **Radiology MRI** |
| Fistula type Superficial | 3 (2%) | 1 (1%) | 4 (1%) |
| Intersphincteric | 14 (9%) | 12 (8%) | 26 (9%) |
| Transsphincteric | 132 (87%) | 138 (90%) | 270 (89%) |
| Supralevator | 0 (-) | 1 (1%) | 1 (<1%) |
| Extrasphincteric | 1 (1%) | 0 (-) | 1 (<1%) |
| Blind Sinus | 1 (1%) | 0 (-) | 1 (<1%) |
| Missing | 1 | 0 | 1 |
|  |  |  |  |
| Extensions present | 41 (27%) | 35 (23%) | 76 (25%) |
|  |
| Number of extensions Median [IQR, N] | 1.0 [1.0-1.0, 41] | 1.0 [1.0-1.0, 35] | 1.0 [1.0-1.0, 76] |
| Range | 1.0-2.0 | 1.0-3.0 | 1.0-3.0 |
|  |  |  |  |
| Location of extensions Intersphincteric | 17/41 (41%) | 19/35 (54%) | 36/76 (47%) |
| Ischioanal fossa | 24/41 (60%) | 18/35 (51%) | 42/76 (56%) |
| Supralevator | 6/41 (15%) | 2/35 (6%) | 8/76 (11%) |